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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/711.855	11/13/2000	Brit Kalatz	RDID0006US	8566

32842 7590 02/24/2003

THE LAW OFFICE OF JILL L. WOODBURN, L.L.C.
JILL L. WOODBURN
128 SHORE DR.
OGDEN DUNES, IN 46368

EXAMINER

LY, CHEYNE D

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 02/24/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/711,855

Applicant(s)

KALATZ ET AL.

Examiner

Cheyne D Ly

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on December 02, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12, and 32-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12, 32 and 34-37 is/are rejected.
- 7) ☒ Claim(s) 33 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 14.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicants' arguments in Paper No.13, filed December 02, 2002, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

2. Claims herein under examination are claims 1-10, 12 and 32-37.

Specification

3. Applicant is reminded of the proper language and format for an abstract of the disclosure.

4. The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The abstract of the instant application exceeds the 150-word limitation. Applicants are advised to replace the abstract of this instant application with one that meets the requirements stated above.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 2-5, 12, 32, 34 and 35 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable

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one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

7. This rejection is maintained with respect to Claims 2-5, 12, 32, 34 and 35, as recited in the previous office action Paper No. 11, mailed June 25, 2002.

8. Specific to claim 2, the factor “E” is a non-enabled value due to R_{KH} not being enabled because it is not directly or indirectly defined in the specification as originally filed. It is acknowledged that the specification discloses that “E” is an empirical factor (Page 12, line 24) and “it is favorable to use $R_{KH} * F$ as E” (Page 11, lines 16-18). Applicants’ argument and pointed to support have been considered, however, they have been found to be unpersuasive. The pointed to support does not provide sufficient guidance for one skilled in the art to derive either “E” or “ R_{KH} ” because the specification uses one undefined term such as R_{KH} to define another undefined term such as “E”. Therefore, it would require undue experimentation for one skilled in the art to derive these factors. Further, Applicants argue that the specification teaches in page 8 lines 14-19, that E is a factor that takes into account the proportionality of the actual glucose value in a projection period and the carbohydrate units that are effective in the projection period. The Examiner has not been able to find the pointed support that defines “E” as stated above. However, the specific pointed to section discloses that “[t]his formula uses the factor KH_j to take into account the consumption of carbohydrates at numerous points in time, as well as the quantity of carbohydrate units consumed each time.”

9. Lastly, Applicants argue that the factor “E” is specifically used in a working example, Figure 5 and page 15 beginning at line 15. The Examiner has not been able to find in the pointed to support, Figure 5 or page 15, line 15, where the disclosure therein enables one skilled in the

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art to derive factor “E” without undue experimentation. It is acknowledged that in the working example factor “E” is used equation (9) for calculating the insulin dosage from the data derived from Figure 5, however, the working example does not disclose the derivation of factor “E”.

Claims 3-5, 32 and 34 are rejected for being directly or indirectly dependent from claim 2.

10. Specific to claim 3, the factor “ R_{KH} ” is a non-enabled value due to the lack disclosure of guidance of how one skilled in the art would derive the value R_{KH} . Applicants argue that R_{KH} is defined in the specification as a carbohydrate reduction factor that is used to reduce the effect of carbohydrate on blood glucose concentration. It is acknowledged that the pointed to support is present in page 11, lines 17-19. However, the pointed to support does not provide sufficient guidance for one skilled in the art to predictably derive the value R_{KH} without undue experimentation. Further, Applicants have directed the Examiner to Fig. 3 for evidence that would enable the derivation of the value of R_{KH} . The support and argument have been found to be unpersuasive because the specification as originally filed does not provide adequate disclosure that would enable one skilled in the art to derive the value R_{KH} . Specific to Figure 3, it is acknowledged that it is a model of the glucose-flooding rate and it is disclosed that the model forms a good basis for the extrapolation of glucose concentration (page 10, lines 1-10). However, the specification does not specifically teach the derivation of the R_{KH} value from the data presented in Figure 3. The specification also discloses that the model of the current invention is one of many such models in the art (page 10, lines 5-10). Therefore, the specification does not provide sufficient guidance for one skilled in the art to predictably derive the R_{KH} value for this particular model without undue experimentation.

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11. Specific to claim 3, the factor “(F)” is a non-enabled value due to the lack of disclosure of guidance of how one skilled in the art would derive the value “(F)”. Applicants’ argument and pointed to support wherein data contained Figure 3 was used to determined values R_{KH} and E; and it is favorable to use R_{KH} (F) as E. Applicants’ argument has been found to be unpersuasive. As stated above, the derivation of the values R_{KH} and E are not present in the specification, therefore, one skilled in the art would not be able to derive the value of (F) based on its relationship with R_{KH} and E. Further, the specification does not specifically disclose the derivation of (F). Therefore, the specification does not provide sufficient guidance for one skilled in the art to derive the (F) value for this particular model without undue experimentation.

12. Further, it is acknowledged that the term “close” is not in the claim, nor is the value 0.25 mmol/l/g. Applicants argue that by pointing to a factor close to 0.25 mmol/l/g as a way of demonstrating the guidance and direction provided in the specification to one skilled in the art to determine its empirical value. Applicants argument has been found to be unpersuasive because by equating a factor (F) to a specific value or one close to it without directions as to how the value was derived does not provide sufficient guidance to one skilled in the art to derive such empirical factor. Unless the (F) factor is a constant well know in the art such as $E=MC^2$ where “C” is the speed of light, one skilled in the art would appreciate equating the constant “C” to a specific value such as light speed. Therefore, the specification does not provide sufficient guidance for one skilled in the art to derive the (F) value for this particular model without undue experimentation.

13. Specific to claims 12 and 35, the value “m” is a non-enabled value due to the lack of disclosure of guidance of how one skilled in the art would derive the value “m”. Applicants’

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argument and pointed to support, Page 8, formula (4), have been found to be unpersuasive. The pointed to support as originally filed does not disclose sufficient guidance and direction for one skilled in the art to derive or conclude that “m” is an integer referring to the last consumption of carbohydrate that is taken into account. Applicants argue “this way of indicating a summation of summation factors is common in mathematics.” Applicants’ argument has been considered and found to be unpersuasive. It is noted that it is well known in the art to use a variable to represent an integer value within an equation for summation. It is further noted it is well known in the art that all variables are specifically defined as to what they represent for the summation calculation. Specific to this instant application, the variable “m” is not defined; therefore, it is not enabled. As originally filed, the variable “m” could symbolize just about anything that is related to a carbohydrate(s) in equation (4). Does “m” represent the number of carbons, hydrogen or oxygen in a carbohydrate? Or does “m” represent a value of the different saccharide units contained within a carbohydrate? The specification does not provide sufficient guidance for one skilled in the art to derive the value “m” without undue experimentation.

14. Applicants argue that “the specification is not required to teach every detail of the invention or to be a production specification”. Applicants’ argument has been found to unpersuasive. It is required that the specification disclose sufficient essential details that one skilled in the art would be enabled to make and use the claimed invention of the particular application or patent. The purpose of the requirement that the specification describe the invention in such terms that one skilled in the art can make and use the claimed invention is to ensure that the invention is communicated to the interested public in a meaningful way. The information contained in the disclosure of an application must be sufficient to inform those

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skilled in the relevant art how to both make and use the claimed invention. Detailed procedures for making and using the invention may not be necessary if the description of the invention itself is sufficient to permit those skilled in the art to make and use the invention.

15. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

16. Claims 5 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

17. Specific to claims 5, line 2 and 32, line 2, the term “includes” causes the claims to be vague and indefinite. It is unclear how the factor, X, can “include” the quantity GB. It is doubtful that one value can “include” another unless the GB quantity is utilized within a formula to calculate the quantity of X.

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

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the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

20. Claims 1, 6-10, 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Worthington et al. (US005822715A) taken with Goldman et al. (US005542420A) in view of Conn et al. (WO 00/47109).

21. Worthington et al. demonstrates a "diabetes management system" (abstract) that includes an apparatus, method and system that determines a predicted value of blood glucose concentrations at specific times as recited in claim 1. The teachings of Worthington et al. as applied to claims 1, 7-10, 36 and 37 are cited in Paper No. 11, mailed June 25, 2002, pages 4-5. However, Worthington et al. does not teach "the consumption of carbohydrates at numerous points in time" or "a memory unit for storing...carbohydrates consumed and their times of consumption." Goldman et al. teaches "the system of the present invention which integrates the technological capabilities of current communication and data processing techniques with accumulation and storage of medical and health-related knowledge relating to individuals. Using various apparatus, including telephonic terminals, such knowledge may be accumulated over time, from multiple and varied sources, such as doctors, hospitals, medical laboratories, pharmacies, dieticians, as well as individual patients themselves" (Column 3, lines 27-35). "To consider an exemplary application, after the basic health and environmental information has been stored for a subject's, edible-consumption information is supplied by the individual, typically on-line, at the time of consumption. Again, using the data input as represented by block 12, the

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individual's eating habits and drug intake are specified and stored. Information from the data input block 12 in the form of a personal health profile is supplied to an evaluation block 14 that also receives pertinent data regarding human needs stored as indicated by an edible-needs block 16. The evaluation block 14 processes the personalized and generic data to arrive at recommended intake quantities (RIQ) for an individual subject. That is, the individual's requirements are defined preliminarily setting forth the various edibles including drugs, vitamins, antioxidants, minerals, proteins, fats, carbohydrates and so on for the specific individual" (Column 6, lines 34-51). Further, Worthington et al. does not teach the device to be a microdialysis device for determining actual glucose concentrations. Conn et al. teaches a system made up of devices and methods to determine the "concentration of an analyte present in a biological system" (Abstract) as applied to glucose monitoring in diabetic patients. Conn et al. teaches a sensing mechanism or device that performs microdialysis (Page 2, line 15) to determine actual glucose concentration in a sample from "across a skin or mucosal surface" (Page 2, line 2).

22. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to practice the diabetes management system of Worthington et al. One of ordinary skill in the art at the time of the invention would have been motivated by the teachings of Goldman et al. to personalize the system of Worthington et al. by integrating the technological capabilities of current communication and data processing techniques with accumulation and storage of medical and health-related knowledge relating to individuals (Column 3, lines 27-30). Further, one of ordinary skill in the art at the time of the invention would have been motivated by the teachings of Conn et al. to modify the monitoring device of Worthington et al. and Goldman

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et al. to perform microdialysis to determine glucose concentrations. Therefore, one of ordinary skill in the art at the time of the invention would have been motivated to personalize the monitoring system of Worthington et al. as taught by Goldman et al. (Abstract) and further, motivated by the need to perform microdialysis to determine glucose concentrations and self-monitoring of blood glucose levels with a "painless and automatic approach" as taught by Conn et al. (Page 1, lines 12-16).

OBJECTED CLAIMS

23. Claim 33 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

CONCLUSION

24. NO CLAIM IS ALLOWED.

25. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.


26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (703) 308-3880. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

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27. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

28. Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

C. Dune Ly
2/20/03


ARDIN H. MARSCHEL
PRIMARY EXAMINER